

SEP - 2 1999



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
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Washington, D.C. 20231

Carol Stratford
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In Re: Patent Term Extension
Application for
U.S. Patent No. 4,197,297

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,197,297, which claims the human drug product Corlopam® (fenoldopam mesylate), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be two years from the approval date of the product.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of two years from the approval date of the product.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of October 13, 1998 (63 Fed. Reg. 54718). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,873) + 3,208 \\ &= 4,145 \text{ days (11.35 years)}\end{aligned}$$

Since the regulatory review period began October 28, 1983, after the patent issue date (April 8, 1980), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The two year limitation of 35 U.S.C. § 156(g)(6)(C) applies in the present situation because the patent was issued and an action described in 35 U.S.C. § 156(g)(6)(B) was taken before the date of enactment of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed two years under 35 U.S.C. § 156(g)(6)(C), the period of extension will be for two years. Since the patent was previously granted an interim extension under 35 U.S.C. § 156(d)(5), the extension will extend from September 23, 1997, the date the product was granted approval for commercial use. See 35 U.S.C. § 156(d)(5)(E)(ii).

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	4,197,297
Granted	:	April 8, 1980
Applicant	:	Joseph Weinstock
Owner of Record	:	SmithKline Beecham Corporation
Title	:	6-Halo-7,8-Dihydroxy-1-(Hydroxyphenyl)- 2,3,4,5-Tetrahydro-1H-3-Benzazepines
Classification	:	424/244
Product Trade Name	:	Corlopam® (fenoldopam mesylate)
Approval Date	:	September 23, 1997
Term Extended	:	Two years
Expiration Date of Extension	:	September 23, 1999

Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: Crystal Plaza Four, Suite 3C23
2201 South Clark Place
Arlington, VA 22202

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin L. Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
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RE: Corlopam®
(fenoldopam mesylate)
FDA Docket No.: 98E-0489